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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,005	09/11/2000	Erich Wanker	V0179/7001	1379

7590

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EXAMINER

GABEL, GAIENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/485,005

Applicant(s)

WANKER ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Restriction Election

1. Applicant's election of Group 1, claims 1-20, filed 12/5/03 is acknowledged and has been entered. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 21-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1-26 are pending. Claims 1-20 are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 102/103

2. In light of Applicant's amendment and arguments, the rejection of claims 1-3, 5-12, and 18-19 under 35 U.S.C. 102(b) as being anticipated by Tateishi et al (Membrane, 1993) is hereby, withdrawn.
3. In light of Applicant's amendment and arguments, the rejection of claims 4 and 17 under 35 U.S.C. 103(a) as being unpatentable over Tateishi et al (Membrane, 1993) in view of Trottier (Nature, 1995) and in further view of Stott et al. (Proc. Natl. Acad. Sci. USA, 1995) is hereby, withdrawn.
4. In light of Applicant's amendment and arguments, the rejection of claims 13-14, 16, and 20 under 35 U.S.C. 103(a) as being unpatentable over Tateishi et al

(Membrane, 1993) in view of Smith (EP 0 293 249) and in further view of Stott et al.

(Proc. Natl. Acad. Sci. USA, 1995) is hereby, withdrawn.

5. In light of Applicant's amendment and arguments, the rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Tateishi et al (Membrane, 1993) in view of Smith (EP 0 293 249) and in further view of Stott et al. (Proc. Natl. Acad. Sci. USA, 1995) as applied to claims 13-14, 16, and 20 above, and further in view of Vitck et al. (US 5,935,927) is hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 lacks clear antecedent support in reciting, "said material" because there is no recitation of "material" in claim 6 from which it depends, and any one of claims 1, 2, and 3 from which claim 6 depends makes reference to "material of a sample". Perhaps, Applicant intends, "wherein said filter" to clarify the claim.

Claim 11 is vague and indefinite because it is unclear how detection is "effected by electron microscopy, ..." especially that in claim 10, "detection ... is effected by an antibody ... that binds to the fibrils or protein aggregates".

The term "preferably" in claim 12 is a relative term which renders the claim indefinite. The term "preferably" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 13 is confusing in reciting, "separates the above mentioned components of the fusion protein further comprising the following steps ...". Perhaps Applicant intends, "separates the above mentioned components of the fusion protein, the method further comprising the following steps ...".

Claim 13 is indefinite in reciting "has the ability to self-assemble" because it fails to recite a positive limitation in the claim.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-12 and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kalchman et al. (US 6,235,879).

Kalchman et al. discussed the role of huntingtin and HIP1 in the pathology of Huntington's disease (HD) in column 2, lines 14-32 and column 5, lines 1-29. Kalchman et al. specifically disclose that the interaction between HD proteins and HIP1 is influenced by the number of polyglutamine repeats and that expanded polyglutamine tracts aggregate into large irregularly shaped deposits in HD brains. In protein preparation and western blotting for expressions studies, proteins were treated with detergent, sodium dodecyl sulphate (separated on SDS-PAGE mini-gels) and HIP1 and huntingtin proteins were captured and detected (transferred and electroblotted) on cellulose acetate filter (PVDF membranes, Immobilon-P, Millipore). Immunoreactivity was determined using antibodies against HIP1 and Huntingtin and visualized in chemiluminescent ECL solution (see column 11, line 63 to column 12, line 20). Kalchman et al. further determined that HIP1 colocalized with Huntingtin in P2 and P3 membrane fractions and that solubilization with non-ionic detergent such as t-octylphenoxypolyethoxyethanol, i.e. Triton X-100, revealed that HIP1 is insoluble to Triton X-100 (see Examples 7 and 8, especially column 11, lines 14-43). According to Kalchman et al., a variety of expression vectors can be transfected to express recombinant HIP modulating proteins or fragments in mammalian cells (see column 7, lines 10-55). Kalchman et al. observed that transfection of a gene encoding a fusion

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protein of 128 repeat Huntingtin and HIP1 (death effector domain) have resulted in aggregate formation in some cells in a cell culture.

Response to Arguments

8. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new grounds of rejection.

Allowable Subject Matter

9. Claims 13-16 are clear of the prior art of record. The prior art of record fails to teach or fairly suggest a fusion protein for use in the method of claim 1, comprising 1) a (poly)peptide that enhances solubility or prevents aggregation of the fusion protein; 2) an amyloidogenic (poly)peptide that self assembles into amyloid-like fibrils or protein aggregates when released from the fusion protein; and 3) a cleavable site that separates 1) and 2) of the fusion protein; and wherein the fusion protein is further incubated with a suspected inhibitor of amyloid-like fibrils and protein aggregate formation, and simultaneously or concurrently, with a compound that induces cleavage at the cleavage site.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
February 26, 2004 *GB*

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~-1641